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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,790	05/15/2007	Enrico Colli	66073US(49949)	1174

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EXAMINER
WEDDINGTON, KEVIN E

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,790	COLLI, ENRICO	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-5,7 and 9-20* is/are pending in the application.

4a) Of the above claim(s) *7,9,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-5 and 10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8-25-06; 3-14-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 3-5, 7 and 9-20 are presented for examination.

Applicant's drawings and preliminary amendment filed August 25, 2006 and the information disclosure statements filed August 25, 2006 and March 14, 2007 have been received and entered.

Applicant's election filed January 13, 2009 in response to the restriction requirement of October 20, 2008 has been received and entered. The applicant elected the invention described in claims 3-5 and 10-18 (Group I) with traverse.

Applicant's traverse is noted, but is not deemed persuasive for reasons set forth in the previous Office action dated October 20, 2008; therefore, the restriction requirement is hereby made Final.

Claims 7, 9, 19 and 20 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 140 of copending Application No. 10/572,995 in view of Beers et al, THE MERCK MANUAL OF MEDICAL INFORMATION, "Interstitial Cystitis", page 869, (2003).

The present application teaches a method for preventing and/or treating interstitial cystitis in a subject comprising administering a vitamin D compound, and the copending application teaches a method for preventing or treating bladder dysfunction with a vitamin D compound. Note that interstitial cystitis is a type of bladder dysfunction, therefore, the copending application's bladder dysfunction encompasses the present application's interstitial cystitis.

Claims 3 and 4 are not allowed.

This is a provisional obviousness-type double patenting rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 3 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/573,164 in view of Beers et al, THE MERCK MANUAL OF MEDICAL INFORMATION, "Interstitial Cystitis", page 869, (2003).

The present application teaches a method for preventing and/or treating interstitial cystitis in a subject comprising administering a vitamin D compound, and the copending application teaches a method for preventing or treating overactive bladder with a vitamin D compound. Note the Beers et al. reference states that interstitial cystitis usually produces a frequent, urgent need to urinate (overactive bladder) as one of its symptoms; therefore, the copending application's overactive bladder encompasses the present application's interstitial cystitis.

Claim 3 is not allowed.

This is a provisional obviousness-type double patenting rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 4 and 10-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-36 and 43 of copending Application No. 11/663,704. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a method for preventing and/or treating interstitial cystitis in a subject comprising administering a vitamin D compound, and the copending application teaches a method for treating a subject for a vitamin D_3 compound wherein the vitamin D_3 is interstitial cystitis. Note that vitamin D compounds of the present application encompass the vitamin D compounds of the copending application.

Claims 3, 4 and 10-18 are not allowed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a written description rejection.

A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

In particular, the specification as original filed fails to provide sufficient written bases of any of the agents demonstrating wherein possession of use of the broad terms: **a vitamin D compound and a second medicament for the treatment of interstitial**

cystitis. The mere fact that Applicant may have discovered one type of vitamin D compound is effective in treating interstitial cystitis is not sufficient to claim the entire genus. Also the addition of one type of a second medicament used to treat interstitial cystitis combined with the preferred vitamin D compound is not sufficient to claim the entire genus of a second medicament.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

Claims 3-5 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-5 and 10-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating interstitial cystitis in a subject with the administration of a vitamin D compound and then administering a second medicament for the treatment of interstitial cystitis, does not reasonably provide enablement for preventing interstitial cystitis in a subject with the administration of a vitamin D compound and then administering a second medicament for the treatment of interstitial cystitis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method for preventing interstitial cystitis in a subject with the administration of a vitamin D compound and then administering a second medicament for the treatment of interstitial cystitis to said subject.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

There are no known preventive therapies for interstitial cystitis in the art.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of any “causes” of interstitial cystitis.

The amount of direction or guidance provided and the presence or absence of working examples

There are no examples showing the instant vitamin D compound will, in fact, prevent interstitial cystitis in a subject not presently at risk of or predisposed to developing such a disease. No examples showing the instant vitamin D compound that is administered to a healthy subject not having interstitial cystitis, and the administration

of the instant vitamin D compound will prevent the subject from becoming infected with interstitial cystitis during its lifetime. Current modes of treatment are known, but there are no known agents, which can be, prevent the causes of interstitial cystitis in a healthy subject.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which cause would be prevented for interstitial cystitis. The skilled artisan would expect the interaction of a particular drug in the prevention of causes of interstitial cystitis to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis of the agent. The instant specification sets forth no such understanding nor any criteria for extrapolating beyond the administration of the vitamin D compound. Even for the data presented, no direction is provided to prevent specific causes of interstitial cystitis. Absent reasonable *a priori* expectations of success, one skilled in the art would have to test extensively many conditions that may lead to interstitial cystitis to discover which cause is prevented. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Claims 3-5 and 10-18 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-5 and 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro (US 2005/0090553 A1, priority date of June 30, 1992) in view of Cartt (US 2001/0034328 A1).

Shapiro teaches compositions and method for the treatment of chronic inflammatory diseases wherein the compositions comprise (1) at least one required primary agent, (2) at least one previously known medicament co-agent effective to treat a chronic inflammatory disease, (3) optionally one or more additional orally consumed co-agent selected from vitamins (see the abstract). Note particularly page 39, claim 2 which states the (2) at least one previously known medicament co-agent effective to treat a chronic inflammatory disease is selected from vitamin D_3 (page 40, line 9), a vitamin D compound. Also note on page 41, claim 4, the optional additional vitamin co-agent includes vitamin D compounds. Finally, note page 43, claim 16, the chronic inflammatory diseases such as interstitial cystitis is treated with this instant composition.

The instant invention differs from the cited reference in that the cited reference does not teach the applicants' preferred vitamin D compounds set forth in claims 10-15. However, one skilled in the art would have assumed that all vitamin D compounds, such as its major forms (vitamin D2 and vitamin D3, its metabolites and other analogs) would posses the anti-inflammatory activities as set forth in the primary reference in the absence of evidence to the contrary.

The instant invention differs from the cited reference in that the cited reference does not teach the applicants' preferred second medicament for the treatment of interstitial cystitis. However, the secondary reference, Cartt teaches the treatment of male chronic pelvic pain syndrome (another term for interstitial cystitis) with the administration of pentosan polysulfate (see page 5, claim 10).

Clearly, one skilled in the art would have assumed the combination of two well-known agents useful to treat interstitial cystitis into a single composition would give an additive effect in the absence of evidence to the contrary.

Claims 3-5 and 10-18 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
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